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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM12/1218

EXAMINER

SLOBODYANSKY, E

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

13
12/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/470,168

Applicant(s)
Boston et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



☒ Responsive to communication(s) filed on Oct 12, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-62 is/are pending in the application.

Of the above, claim(s) 1-14 and 52-57 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 15-51 and 58-62 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

Claims 1-14, 52-57 and in part 47-51, 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups I and III, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8 filed October 12, 2000.

Applicant's election of Group II, claims 15-46, 59-62 and in part claims 47-51, 58 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

This application contains no IDS.

Specification

The specification is objected to because it refers to D-gluconate dehydrogenase(GDH) where it appears glucose dehydrogenase (GDH) is intended (page 21, lines 7-8).

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Claim Objections

Claim 36 is objected to because of the following informalities: a period is missing at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-46, 59-62 and claims 47-51, 58(in part) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 15 is directed to a method for the non-fermentative production of 2-KLG from a carbon source comprising oxidizing the carbon source and reducing the resulting oxidation product to 2-KLG. The dependent claims recite the specific oxidizing or reducing activities, a source thereof, a specific co-factor and specific carbon source. Therefore, the claims encompass pathways from any carbon source to KLG through any intermediate. The specification discloses oxidation of glucose to gluconate by glucose dehydrogenase and than gluconate by gluconate dehydrogenase and 2-KDG

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dehydrogenase to DKG. DKG is then reduced to 2-KLG. This pathway is known in the art. The specification fails to describe other representative reactions that produce 2-KLG from any carbon source. Therefore, said reactions are characterized only by the final product, 2-KLG. A starting material, a carbon source, includes a vast genus of different functionally and structurally unrelated compounds. Therefore, the claims are drawn to a method of use of a genus of molecules described by broad function (oxidation/reduction). Therefore, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. No common structural attributes identify the members of the genus. Given this lack of description of common structural attributes or characteristics that identify members of the genus of enzymes catalyzing the specific reaction, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 15-51 and 58-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing 2-KLG from glucose using glucose dehydrogenase, gluconate dehydrogenase, 2-KDG dehydrogenase and reductase A:F22Y/A272G, does not reasonably provide enablement for producing 2-KLG from any carbon source using any oxidase and reductase. The specification does

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not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 15-51 and 58-62 are so broad as to encompass any combination of oxidase/reductase catalyzing unspecified reactions. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of potential enzymes broadly encompassed by the claims. However, in this case the disclosure is limited to producing 2-KLG from glucose using glucose dehydrogenase, gluconate dehydrogenase, 2-KDG dehydrogenase and reductase A:F22Y/A272G.

The general pathway for producing 2-KLG from glucose disclosed in the specification is known in the art. The specification provides no guidance as to what are other oxidation/reduction reactions that can produce 2-KLG from any source comprising carbon.

The specification does not support the broad scope of the claims which encompass all oxidases and reductases because it is known in the art that enzymes are highly substrate specific. The specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated

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with the scope of the claims broadly including any carbon source as a starting material from which any number of oxidases and reductases produce 2-KLG. Without sufficient guidance, determination of enzymes having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites enzyme which is "a dehydrogenase activity". Claim 27 recites enzyme which is "a GADH activity". An enzyme has an activity, it is not an activity itself.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-51 and 58-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Light et al.

Light et al. (US Patent 4,758,514) teach the pathway glucose - 2-KLG (column 1, lines 16--29). They further teach the production of 2-KLG from glucose by *Erwinia* cell transformed with 2,5-DKG reductase gene (column 17, line 62 through column 20, line 5, Examples 5 and 6). This process comprises enzymatical oxidation of glucose by *Erwinia* into DKG and enzymatical reduction of DKG to 2-KLG. Since enzymes involved in oxidation of glucose to DKG are known in the art it would have been obvious to the one of ordinary skill in the art at the time the invention was made to carry out non-fermentative oxidation of glucose into DKG using purified enzymes or cells transformed with a DNA encoding an enzyme. One would have been motivated to use non-fermentative oxidation of glucose into DKG as a matter of convenience.

Claims 15-51 and 58-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powers et al.

Powers et al. (US Patent 5,795,761) teach the pathway glucose - 2-KLG. They further teach that a number of microorganisms such as *Erwinia*, *Acetobacter* and

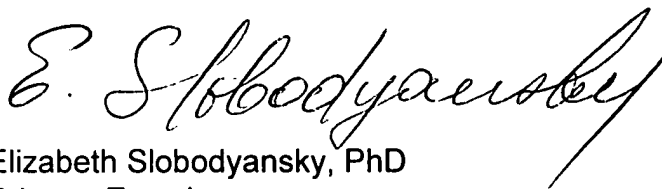
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Gluconobacter can produce 2,5-DKG from glucose and the second group can reduce 2,5-DKG to 2-KLG (column 1, lines 25-61). They teach reductase A:F22Y/A272G mutant (Figure 10, for example) catalyzing conversion of 2,5-DKG to 2-KLG. . Since enzymes involved in oxidation of glucose to DKG are known in the art it would have been obvious to the one of ordinary skill in the art at the time the invention was made to carry out non-fermentative oxidation of glucose into DKG using purified enzymes or cells transformed with a DNA encoding an enzyme. One would have been motivated to use non-fermantative oxidation of glucose into DKG as a matter of convenience.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner

December 15, 2000